K082288

Jiangyin East China Medical Technology Co., Ltd.
No.555, Qinfeng Road, Huashi Town, Jiangyin City, Jiangsu, China, 214421
TEL: +86-510-86218310 FAX: +86-510-86218308

510(k) Summary

AUG 19 2008

Device

Trade name: **HAIDA HD21 powered wheelchair**

Common name: **Powered wheelchair**

Classification name: **Powered wheelchair**

Medical specialty (Panel): **Physical Medicine Device**

Regulation number: **890.3860**

Product Code: **ITI**

Classification: **Class II**

Predicate devices

CWD01 (K062888) / EMG Technology Co. Ltd.

KV10HB(K072027) / KWANG YANG MOTOR CO., LTD.

Intend use of device

HAIDA HD21 powered wheelchair is intended for an indoor/outdoor power wheelchair that provides transportation for disabled or elderly persons limited to a seated position.

Device description:

The **HAIDA HD21** powered wheelchair is an indoor/outdoor powered wheelchair that is battery operated. The design of this wheelchair is basically similar to other powered wheelchairs that are already on the market.

Substantial equivalence:

The **HAIDA HD21 powered wheelchair** is substantially equivalent to the **CWD01 (K062888)** and **KV10HB(K072027)** manufactured by **EMG Technology Co. Ltd.** and **KWANG YANG MOTOR CO., LTD.**, respectively.

There are minor differences in performance specifications of the powered wheelchairs, these differences do not alter the intended function and use of the device, nor do they raise any new questions pertaining to safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Jiangyin East China Medical Technology Company., Ltd
% Junnata Chang, Ph.D.
14F-2 NO. 1 Lane 25
Zhuangjing Road
Banqiao,
China (Taiwan) 220

AUG 19 2008

Re: K082288
Trade/Device Name: HAIDA HD 21
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair.
Regulatory Class: Class II
Product Code: ITI
Dated: July 20, 2008
Received: August 11, 2008

Dear Dr. Chang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for use

510(k) Number (if known): _____

Device Name: **HAIDA HD21**

Indications for use:
It is a motor driven, indoor and outdoor transportation vehicles with the intended use to provide mobility to disabled or elderly persons limited to a seated position.

Prescription Use _____ Over-The-Counter Use __X__
(Part 21 CFR 801 Subpart D) AND/OR (Part 21 CFR 807 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE) Page 1 of 1

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K042288

(Posted November 13, 2003)